Complete Summary

GUIDELINE TITLE

Quality indicators for endoscopic ultrasonography.

BIBLIOGRAPHIC SOURCE(S)

Jacobson BC, Chak A, Hoffman B, Baron TH, Cohen J, Deal SE, Mergener K, Petersen BT, Petrini JL, Safdi MA, Faigel DO, Pike IM. Quality indicators for endoscopic ultrasonography. Gastrointest Endosc 2006 Apr;63(4 Suppl):S35-8. [23 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Gastrointestinal and mediastinal mass lesions

GUIDELINE CATEGORY

Diagnosis
Evaluation

CLINICAL SPECIALTY

Gastroenterology

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To establish quality indicators to aid in the recognition of high-quality endoscopic ultrasonography (EUS) examinations

TARGET POPULATION

Patients undergoing endoscopic ultrasonography

INTERVENTIONS AND PRACTICES CONSIDERED

Endoscopic ultrasonography

MAJOR OUTCOMES CONSIDERED

Safety and efficacy of procedure

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Studies were identified through a computerized search of Medline followed by review of the bibliographies of relevant articles. When such data were absent, indicators were chosen by expert consensus.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The American Society for Gastrointestinal Endoscopy (ASGE) and the American College of Gastroenterology (ACG), as leaders in promoting the highest quality patient care, formed a task force to identify end points that could be used to document high-quality endoscopic services. In most cases these end points will require validation before they can be generally adopted. The task force consisted of expert endoscopists selected by the board of directors of the ASGE and the ACG.

The task force developed quality indicators for the 4 major endoscopic procedures: colonoscopy, esophagogastroduodenoscopy (EGD), endoscopic retrograde cholangiopancreatography (ERCP), and endoscopic ultrasonography (EUS). Wherever possible, these indicators were chosen because there were published supporting data. These studies were identified through a computerized search of Medline followed by review of the bibliographies of relevant articles. When such data were absent, indicators were chosen by expert consensus. The goal was to create a comprehensive list of potential quality indicators, recognizing that only a small subset may ultimately be implemented. The resultant quality indicators were graded on the strength of the supporting evidence.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendation

Grade of recommendation	Clarity of benefit	Methodologic strength/supporting evidence	Implications
1A	Clear	Randomized trials without important limitations	Strong recommendation; can be applied to most clinical settings
1B	Clear	Randomized trials with important limitations (inconsistent results, nonfatal methodologic flaws)	Strong recommendation; likely to apply to most practice settings
1C+	Clear	Overwhelming evidence from observational studies	Strong recommendation; can apply to most practice

Grade of recommendation	Clarity of benefit	Methodologic strength/supporting evidence	Implications
			settings in most situations
1C	Clear	Observational studies	Intermediate-strength recommendation; may change when stronger evidence is available
2A	Unclear	Randomized trials without important limitations	Intermediate-strength recommendation; best action may differ depending on circumstances or patients' or societal values
2B	Unclear	Randomized trials with important limitations (inconsistent results, nonfatal methodologic flaws)	Weak recommendation; alternative approaches may be better under some circumstances
2C	Unclear	Observational studies	Very weak recommendation; alternative approaches likely to be better under some circumstances
3	Unclear	Expert opinion only	Weak recommendation; likely to change as data become available

*Adapted from Guyatt G, Sinclair J, Cook D, Jaeschke R, Schunemann H, Pauker S. Moving from evidence to action: grading recommendations—a qualitative approach. In: Guyatt G, Rennie D, eds. Users' guides to the medical literature. Chicago: AMA Press; 2002. p. 599-608.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The task force consisted of expert endoscopists selected by the board of directors of the American Society for Gastrointestinal Endoscopy (ASGE) and the American College of Gastroenterology (ACG). These documents were then reviewed and approved by the governing boards.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Recommendations were graded on the strength of the supporting evidence (Grades 1A - 3). Definitions of the recommendation grades are presented at the end of the "Major Recommendations" field.

Preprocedure Quality Indicators

1. Proper indication. Endoscopic ultrasonography (EUS) should be performed for an acceptable indication as defined by the American Society for Gastrointestinal Endoscopy (ASGE). Acceptable indications have been published previously (ASGE, 2000). **(3)**

   Discussion. Although there are many instances in which EUS can be performed, the necessity of the procedure in the care of any particular patient depends on its impact on management and the superiority of EUS over other available imaging or surgical procedures. This implies a certain degree of clinical judgment in choosing if and when to perform EUS in relation to other procedures, making rigid indications inadvisable. That being said, expert opinion has identified specific clinical situations for which EUS is deemed an appropriate diagnostic or therapeutic procedure (Table below). It is fully expected that certain indications may change with time. In addition, the appropriate use of EUS also depends in part upon the availability of other imaging methods because not all patients will have reasonable access to alternatives to EUS.

   It is also recognized that there may be unforeseen circumstances in which EUS can provide clinically useful information. For this reason, 100% compliance with predetermined indications is considered restrictive. However, the inclusion of an indication in the procedure documentation for all cases is considered a useful quality measure for 2 reasons. First, it provides a justification for the procedure and serves as a means of tracking compliance with accepted indications. In addition, the indication places the remainder of the procedure report in a specific context wherein certain endosonographic landmarks and finding characteristics should logically follow. For example, detailed descriptions of the pancreas may not be necessary when the indication for EUS is esophageal cancer staging. However, once esophageal cancer staging is provided as the indication, certain components of the examination, such as T and N staging, including celiac axis visualization barring nontraversibility, are expected and their subsequent inclusion would reflect a thorough EUS.

Table: Acceptable Indications for EUS According to the ASGE

1. Staging of tumors of the gastrointestinal (GI) tract, pancreas, bile ducts, and mediastinum
2. Evaluating abnormalities of the GI tract wall or adjacent structures
3. Tissue sampling of lesions within, or adjacent to, the wall of the gastrointestinal tract
4. Evaluation of abnormalities of the pancreas, including masses, pseudocysts, and chronic pancreatitis
5. Evaluation of abnormalities of the biliary tree

6. Providing endoscopic therapy under ultrasonographic guidance

2. Proper consent. Consent should be obtained and documented for every procedure. In addition to the risks associated with all endoscopic procedures, the consent should address the relevant and substantial complications pertaining to each specific EUS procedure. **(3)**

   Discussion. EUS and EUS-fine-needle aspiration (FNA) present some unique complication risks beyond those associated with standard endoscopy. A review of the complications specific to EUS have been published previously. In some instances, EUS requires passage of large echoendoscopes or endoscopes with relatively rigid portions. This has been associated with an increased risk of perforation. Perforation risk may also be higher when staging esophageal cancer, particularly in the setting of pre-EUS dilation of an obstructing malignancy. FNA introduces an increased risk of infection and hemorrhage, as well as pancreatitis when FNA of a pancreatic lesion is performed. Finally, a risk of tumor seeding along the FNA tract has been reported in very rare circumstances. Celiac plexus neurolysis or celiac plexus block (CPN or CPB) carry unique risks of hypotension and diarrhea, in addition to the standard risks.

3. Prophylactic antibiotics. Antibiotics should be administered in the setting of fine-needle aspiration (FNA) of cystic lesions. **(2C)**

   Discussion. There have been no randomized trials conducted to determine the need for prophylactic antibiotics in the setting of EUS-FNA of cystic lesions. One study examining the efficacy of EUS-FNA found no clinically significant bacteremia resulting from FNA of solid lesions. However, a subgroup analysis of patients with cysts undergoing FNA demonstrated a 14% risk of infectious complications. There have also been reports of mediastinitis complicating FNA and tru-cut needle biopsy of bronchogenic cysts. This has led to the American Society for Gastrointestinal Endoscopy recommendation that prophylactic antibiotics be administered to all patients undergoing EUS-FNA of pancreatic cystic lesions.

Intraprocedure

4. Visualization of structures of interest. There should be documentation of the appearance of relevant structures, specific to the indication for the EUS. Specific quality indicators identified are as follows: **(3)**
   a. In the setting of esophageal cancer staging without obstruction, celiac axis visualization should be documented.
   b. In the setting of evaluating for the presence of pancreatic disease, visualization of the entire pancreas should be documented.

   Discussion. To maximize clinical efficacy, EUS should provide all pertinent information relevant to the procedure's indication. The endosonographer must visualize specific structures depending on the disease process being investigated and must subsequently document these findings in writing or with photo documentation.

5. Description of abnormalities. **(3)**

    a. All gastrointestinal cancers are staged with the American Joint Commission for Cancer (AJCC)/Union Internationale Contre le Cancre (UICC) TNM staging system. (AJCC, 2002; Sobin & Wittekind, 2002)
    b. Pancreatic mass measurements are documented.
    c. The EUS wall layers involved by subepithelial masses are documented.

    Discussion. A diagnosis based on EUS findings, with or without cytologic examination from FNA, requires not only an accurate localization and description of sonographic findings, but also an accurate interpretation of these findings within the individual patient's clinical context. Currently the AJCC/UICC TNM systems are the most widely used methods for staging gastrointestinal malignancies. Therefore, to maximize the utility of EUS in the setting of cancer staging, the elements necessary to assign both T and N stages should be obtained during the procedure and documented in writing and with saved images. This includes measurements of pancreatic masses because T staging may depend on tumor size.

    In the setting of subepithelial lesions, the differential diagnosis is based on wall layer of origin, echo characteristics, and size of lesion. Therefore, these findings should be documented in every report.

6. Appropriate use of biopsy. EUS-guided FNA is performed of celiac axis lymph nodes discovered at EUS staging of thoracic esophageal cancer. **(2C)**

    Discussion. The additional clinical information obtained from FNA can increase the diagnostic accuracy of EUS significantly by confirming a pathologic diagnosis, obtaining more accurate nodal staging in malignancy, and yielding fluid for various analyses, including chemical analyses, tumor markers, and bacterial/fungal stains or culture. It is also recognized that FNA is not feasible or appropriate in all conditions. For example, it is acknowledged that FNA through a tumor to obtain tissue from an adjacent lymph node may yield a false-positive result. It therefore becomes impossible to suggest a fixed percentage of EUS cases in which FNA should be done. However, when FNA is appropriate, the endosonographer should make every effort to incorporate this step into the EUS.

    In the setting of esophageal cancer in the thoracic esophagus, malignant celiac axis lymph nodes confer M1a status and alter patient management. It has also been shown that echo characteristics alone are not sufficiently accurate in predicting metastatic involvement of lymph nodes. The involvement of an on-site cytopathologist during EUS-FNA may help limit the number of FNA passes taken or increase the overall diagnostic accuracy of the procedure. However, it is recognized that not all endosonographers will have access to this degree of service. Therefore, in situations where a cytopathologist or cytotechnologist is not available, several FNA passes should be made to maximize sensitivity. For lymph nodes, prospective studies have suggested that 3 to 5 passes are adequate to maximize sensitivity.

Postprocedure

7. Complication rates. The incidence of pancreatitis after EUS-FNA of the pancreas is measured. **(1C)**

   Discussion. Patients undergoing EUS-FNA of the pancreas are at risk for development of pancreatitis, likely as a result of direct tissue injury as the needle traverses pancreatic tissue. The incidence of pancreatitis in this setting, including data from prospective series, has ranged between 0% and 2%.

Definitions:

Grades of Recommendation

Grade of recommendation	Clarity of benefit	Methodologic strength/supporting evidence	Implications
1A	Clear	Randomized trials without important limitations	Strong recommendation; can be applied to most clinical settings
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1C	Clear	Observational studies	Intermediate-strength recommendation; may change when stronger evidence is available
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CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

A high quality endoscopy ensures that the patient receives an indicated procedure, that correct and clinically relevant diagnoses are made (or excluded), that therapy is properly performed, and that all these are accomplished with minimal risk.

POTENTIAL HARMS

Endoscopic ultrasonography (EUS) and EUS-fine-needle aspiration (FNA) present some unique complication risks beyond those associated with standard endoscopy. In some instances, EUS requires passage of large echoendoscopes or endoscopes with relatively rigid portions. This has been associated with an increased risk of perforation. Perforation risk may also be higher when staging esophageal cancer, particularly in the setting of pre-EUS dilation of an obstructing malignancy. FNA introduces an increased risk of infection and hemorrhage, as well as pancreatitis when FNA of a pancreatic lesion is performed. Finally, a risk of tumor seeding along the FNA tract has been reported in very rare circumstances. Celiac plexus neurolysis or celiac plexus block (CPN or CPB) carry unique risks of hypotension and diarrhea, in addition to the standard risks.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Underlying this discussion of quality indicators is the assumption that adequate training and credentialing has taken place before a practitioner begins the practice of endoscopy. The American Society for Gastrointestinal Endoscopy (ASGE) has guidelines specifically addressing standards for training, assessing competence, and granting privileges to perform

endoscopy. It is the task force's recommendation that these guidelines be adopted by facilities where endoscopic procedures are performed.
- The list of potential quality indicators was meant to be a comprehensive listing of measurable endpoints. It is not the intention of the task force that all end points be measured in every practice setting. In most cases, validation may be required before a given end point may be universally adopted.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Jacobson BC, Chak A, Hoffman B, Baron TH, Cohen J, Deal SE, Mergener K, Petersen BT, Petrini JL, Safdi MA, Faigel DO, Pike IM. Quality indicators for endoscopic ultrasonography. Gastrointest Endosc 2006 Apr;63(4 Suppl):S35-8. [23 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Apr

GUIDELINE DEVELOPER(S)

American College of Gastroenterology - Medical Specialty Society
American Society for Gastrointestinal Endoscopy - Medical Specialty Society

SOURCE(S) OF FUNDING

American Society for Gastrointestinal Endoscopy

GUIDELINE COMMITTEE

American Society for Gastrointestinal Endoscopy/American College of Gastroenterology (ASGE/ACG) Taskforce on Quality in Endoscopy

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Taskforce Members: Brian C. Jacobson, MD, MPH; Amitabh Chak, MD; Brenda Hoffman, MD; Todd H. Baron, MD; Jonathan Cohen, MD; Stephen E. Deal, MD; Klaus Mergener, MD, PhD; Bret T. Petersen, MD; John L. Petrini, MD; Michael A. Safdi, MD; Douglas O. Faigel, MD (*ASGE Co-Chair*) Irving M. Pike, MD (*ACG Co-Chair*)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American Society for Gastrointestinal Endoscopy Web site.

Print copies: Available from the American Society for Gastrointestinal Endoscopy, 1520 Kensington Road, Suite 202, Oak Brook, IL 60523

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Bjorkman, DJ, Popp, JW. Measuring the quality of endoscopy. Gastrointest Endosc 2006 Apr;63(4 Suppl):S1-2. Available in Portable Document Format (PDF) from the American Society for Gastrointestinal Endoscopy Web site.
- Faigel, DO, Pike, IM, Baron, TH, Chak, A, Cohen, J, Deal, SE, Hoffman, B, Jacobson, BC, Mergener, K, Petersen, BT, Petrini, JL, Rex, DK, Safdi, MA. Quality indicators for gastrointestinal endoscopic procedures: an introduction. Gastrointest Endosc 2006 Apr;63(4 Suppl):S3-9. Available from the American Society for Gastrointestinal Endoscopy Web site.

Print copies: Available from the American Society for Gastrointestinal Endoscopy, 1520 Kensington Road, Suite 202, Oak Brook, IL 60523

PATIENT RESOURCES

None available

NGC STATUS

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